

Press Release

Nicox: First Half 2019 Financial Results and Business Update

- **H1 2019 net revenue¹ of €5.6 million and net loss² of €0.8 million**
- **Enrollment completed in NCX 470 Phase 2 *DOLOMITES* clinical trial in patients with glaucoma or ocular hypertension. Top-line results on track for early Q4 2019**
- **Collaboration in the Chinese market further strengthened with ZERVIAE and NCX 4251 transactions with Ocumension Therapeutics**
- **Top-line results of NCX 4251 Phase 2 clinical trial on track for Q4 2019**

September 17, 2019 – release at 7:30 am CET
Sophia Antipolis, France

Nicox SA (Euronext Paris: FR0013018124, COX), an international ophthalmology company, today reported the financial results for Nicox and its subsidiaries (the “Nicox Group”) for the six months ending June 30, 2019 and provided an update on its activities as well as key upcoming milestones.

Michele Garufi, Chairman and Chief Executive Officer of Nicox, said: *“This is a compelling and potentially transformative time for Nicox, as we make strong progress in our growth strategy. Our two Phase 2 clinical trials have progressed in accordance with our expected timeline, with data expected early in the fourth quarter for our lead product candidate NCX 470 for glaucoma and later in the year for NCX 4251 in blepharitis. We are optimizing the value of our assets through licensing agreements outside of the U.S. and Europe, including the recent deal for NCX 4251 in the Chinese market, and continuing discussions with potential partners in several markets. With solid foundations in place, we are very much looking forward to continuing the exciting development of our company.”*

Key Upcoming Clinical Milestones

- **NCX 470 Phase 2 results:** Top-line data from the Phase 2 “*DOLOMITES*” safety and efficacy clinical trial, for the lowering of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension expected on time early in the fourth quarter of this year.
- **NCX 4251 Phase 2 results:** Safety and tolerability clinical trial in patients with acute exacerbations of blepharitis progressing as planned, with top-line data expected in the fourth quarter of this year.

Product and Product Candidates Updates

- Enrollment of patients completed in the *DOLOMITES* trial, our multicenter, U.S. Phase 2 safety and efficacy clinical trial evaluating **NCX 470, a novel second generation nitric oxide (NO)-donating bimatoprost analog**, in patients with glaucoma or ocular hypertension. This trial is a head-to-head comparison of once-daily administration of three different doses of NCX 470 versus latanoprost, 0,005%, which is the most widely prescribed first-line therapy for glaucoma and ocular hypertension. The primary endpoint of this trial is the mean reduction in diurnal IOP after 28 days of treatment, while the overall objective is to identify the appropriate dose of NCX 470 to be advanced into Phase 3 trials. 433 patients were randomized at clinical sites across the U.S. and top-line data is expected early in the fourth quarter of this year. In December 2018, Nicox entered into an exclusive license agreement

with Ocumension Therapeutics, Inc. for the development and commercialization of NCX 470 in the Chinese market.

- The Phase 2 safety and tolerability clinical trial of **NCX 4251, a novel, patented ophthalmic suspension of fluticasone propionate nanocrystals**, in patients with acute exacerbations of blepharitis, is on track with top-line data expected in the fourth quarter of this year. The next stage of development will be a larger Phase 2b clinical trial. In July 2019, Nicox entered into an exclusive license agreement with Ocumension for the development and commercialization of NCX 4251 in the Chinese market and received a €2.0 million upfront payment from Ocumension.
- Completed regulatory and manufacturing responsibilities concerning **ZERVIAE (cetirizine ophthalmic solution), 0.24%** in the U.S., and received a \$3.0 million milestone payment from U.S. partner Eyevance Pharmaceuticals. From now on, all manufacturing and regulatory responsibilities, together with decisions on launch timing, lie with Eyevance. Eyevance has informed Nicox that the launch of ZERVIAE in the U.S. is currently projected in the first half of 2020. ZERVIAE is also partnered with Ocumension in the Chinese market pursuant to an exclusive license agreement that it entered into with Ocumension in March 2019.
- **VYZULTA® (latanoprostene bunod ophthalmic solution), 0.024%** is now marketed in Canada, in addition to the U.S., by global partner Bausch + Lomb. Nicox has received royalties since December 2017 from this collaboration. The total number of prescriptions for VYZULTA in the U.S. in the first half of 2019 increased by 54% compared to the second half of 2018³ and by 228% compared to the first half of 2018³.
- Research activities continue to advance with first data presented at ARVO 2019 on **NO-donating phosphodiesterase-5 (PDE5) inhibitors**, a new drug class designed to lower IOP, in which NCX 1741, the first lead molecule from the PDE5 inhibitor program, showed a substantial lowering of IOP in a non-human primate model of ocular hypertension. Nicox expects to announce an IND-track candidate from our NO-donating PDE5 research program in 2020. Research activities are focused on combining NO-donation with other complementary mechanisms of action which are not currently utilized in any approved ophthalmic product, including PDE5 inhibition and soluble guanylate cyclase stimulation. Molecules from these classes could be developed either as adjunctive therapies or in fixed-dose combinations with latanoprost or other prostaglandin analogs for IOP lowering.

First Half 2019 Financial Highlights

Net revenue¹ for the first half of 2019 was €5.6 million versus €0.3 million for the first half of 2018.

Operating expenses for the first half of 2019 were €11.4 million compared to €10.0 million for the first half of 2018. The increase in operating expenses was mainly due to costs associated with the two ongoing Phase 2 clinical trials for NCX 470 and NCX 4251.

- The Nicox Group recorded a net loss of €0.8 million for the six months ended June 30, 2019, compared to a net loss of €7.6 million for the same period in 2018. The net loss in the first half of 2019 has been reduced due to the contribution of the €2.0 million upfront payment and the \$3.0 million milestone payment respectively invoiced to our partners Ocumension and Eyevance, the royalties received from Bausch + Lomb for VYZULTA and the recognition of non-cash income of €3.8 million for deferred tax assets recognized by our U.S. subsidiary.
- As of June 30, 2019, the Nicox Group had cash and cash equivalents of €17.3 million, adjusted to €22.0 million including license payments recorded as revenue in June 2019 but paid in July 2019, as compared with €23.5 million at March 31, 2019 and €22.1 million at year end December 31, 2018.
- As of June 30, 2019, the Nicox Group had financial debt of €7.4 million in the form of a bond financing agreement with Kreos Capital signed in January 2019. Nicox drew down a first tranche of €8.0 million in January 2019 under the agreement and has the option but not the obligation to draw down either €7.0 million or €12.0 million on November 1, 2019, subject to notice to Kreos by October 10, 2019.

Full details of the bond financing agreement can be found in the Press Release of January 25, 2019 - http://www.nicox.com/assets/files/EN- Kreos-PR_201901.pdf.

References

1. Net revenue consists of revenue from collaborations less royalty payments which we refer to as net profit from collaborations in the condensed consolidated statements of profit or loss for the six-month period ended June 30, 2019.
2. Net loss reduced due to exceptional licensing income and non-cash deferred tax income.
3. Bloomberg data, comparing the period of the weeks ending 4 January 2019 to 28 June 2019 with the periods of the weeks ending 6 July 2018 to 28 December 2018 and 5 January 2018 to 29 June 2018.

The diligences related to the half-year review were performed by the auditors. The review report will be issued once procedures will be finalized over the half-year financial report.

About Nicox

Nicox S.A. is an international ophthalmology company developing innovative solutions to help maintain vision and improve ocular health. By leveraging our proprietary expertise in nitric oxide (NO) donation and other technologies, we are developing an extensive portfolio of novel product candidates that target multiple ophthalmic conditions, including glaucoma. Our portfolio has three programs in development including NCX 470, a novel, second-generation NO-donating bimatoprost analog, for intraocular pressure lowering, based on our proprietary NO-donating research platform and NCX 4251, a proprietary formulation of the well-established molecule fluticasone, for acute exacerbations of blepharitis. Our research activities are focused on novel future generation NO-donors including NO-donating phosphodiesterase-5 (PDE5) inhibitors and NO-donating soluble guanylate cyclase (sGC) stimulators (in partnership with Cyclerion). In addition, we have two ophthalmology assets that have been approved by the U.S. Food and Drug Administration (FDA): VYZULTA® (latanoprostene bunod ophthalmic solution), 0.024%, exclusively licensed worldwide to Bausch + Lomb, a Bausch Health Companies Inc. company, and commercialized in the U.S. by Bausch + Lomb since December 2017, as well as ZERVIA™ (cetirizine ophthalmic solution), 0.24%, exclusively licensed in the U.S. to Eyevence Pharmaceuticals, LLC.

Nicox is headquartered in Sophia Antipolis, France, is listed on Euronext Paris (Compartment B: Mid Caps; Ticker symbol: COX) and is part of the CAC Healthcare, CAC Pharma & Bio and Next 150 indexes.

For more information on Nicox, its products or pipeline, please visit: www.nicox.com.

Analyst coverage

Bryan, Garnier & Co	Hugo Solvet	Paris, France
H.C. Wainwright & Co	Yi Chen	New York, U.S.
Oppenheimer & Co	Hartaj Singh	New York, U.S.



The views expressed by analysts in their coverage of Nicox are those of the author and do not reflect the views of Nicox. Additionally, the information contained in their reports may not be correct or current. Nicox disavows any obligation to correct or to update the information contained in analyst reports.

Upcoming Conferences

Bryan, Garnier & Co European Healthcare Conference	12 - 13 November, 2019	Paris
Actionaria,	21-22 November, 2019,	Paris

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Forward-Looking Statements

The information contained in this document may be modified without prior notice. This information includes forward-looking statements. Such forward-looking statements are not guarantees of future performance. These statements are based on current expectations or beliefs of the management of Nicox S.A. and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Nicox S.A. and its affiliates, directors, officers, employees, advisers or agents, do not undertake, nor do they have any obligation, to provide updates or to revise any forward-looking statements.

Risks factors which are likely to have a material effect on Nicox's business are presented in the 4th chapter of the '*Document de référence, rapport financier annuel et rapport de gestion 2018*' filed with the French *Autorité des Marchés Financiers* (AMF) on March 6, 2019 which are available on Nicox's website (www.nicox.com).

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INTERIM CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

	6 Months period ending June 30,	
	2019	2018
	<i>(in thousands of €)</i>	
Revenues from collaborations	6,214	503
Royalty payments	(624)	(203)
Net Profit from collaborations	5,590⁽¹⁾	300⁽¹⁾
Research and development expenditures	(7,539)	(5,816)
Administrative expenses	(3,720)	(4,108)
Other income	489	986
Other expenses	(97)	(100)
Operating loss before amortization of intangible assets	(5,277)	(8,738)
Amortization of intangible assets	(17)	-
Operating loss	(5,294)	(8,738)
Finance income	1,458	1,254
Finance expense	(714)	(70)
Net financial income/(expense)	744	1,184
Loss before tax	(4,550)	(7,554)
Income tax (expense) / benefit	3,799 ⁽²⁾	(96)
Net loss for the period	(751)	(7,650)

⁽¹⁾ Including €0.9 million of net royalties for the six months ended June 30, 2019 against €0.3 million for the six months ended June 30, 2018 and license fees for €4.7 million for the six months ended June 30 2019 against €0.0 million for the six months ended June 30, 2018.

⁽²⁾ Non-cash income tax for deferred tax assets recognized by our U.S subsidiary.

INTERIM CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	As of June 30, 2019	As of Dec. 31, 2018
<i>(in thousands of €)</i>		
ASSETS		
Non-current assets		
Goodwill	25,515	25,359
Intangible assets	71,830	71,397
Property, plant and equipment	694	269
Non-current financial assets	16,310	15,473
Total non-current assets	114,349	112,498
Current assets		
Trade receivables	5,495	616
Government grants receivables	1,612	1,247
Other current assets	1,179	691
Prepayments	1,072	1,479
Cash and cash equivalents	17,354	22,059
Total current assets	26,712	26,092
TOTAL ASSETS	141,061	138,590
EQUITY AND LIABILITIES		
Shareholder's equity		
Issued capital	29,910	29,719
Share premium	510,491	510,683
Cumulative translation adjustment	7,013	6,697
Treasury shares	-	-
Accumulated deficit	(432,992)	(433,445)
Total Equity	114,422	113,653
Non-current liabilities		
Non-current financial liabilities	6,921	54
Deferred tax liabilities	12,793	16,373
Provisions	547	441
Total non-current liabilities	20,261	16,868
Current liabilities		
Current financial liabilities	945	31
Trade payables	3,497	4,281
Deferred income	109	1,256
Provisions	95	76
Other current liabilities	1,732	2,425
Total current liabilities	6,378	8,069
TOTAL LIABILITIES AND EQUITY	141,061	138,590